

The central problem which Little addresses is what he sees as increasing difficulty and failure of communication between doctors and patients, leading, along with other factors, to a loss of esteem for the profession. "Government control, hostile media, complaints departments and increasing litigation warn that the communication barriers are harming the standing of the medical profession, and threatening to limit the very real good that it has the power to do." Little sees the "reductionist" emphasis of a largely science-based medical curriculum as a hindrance to the development of communication skills by doctors; and calls for "a new medicine", with greater emphasis on "an empathic stance", and for "a conscious change from a medical model which is biopositive to one which is biohumane". Science deals with generalisations and groups; whereas the practice of medicine deals with individuals and their specific problems. "The uniqueness of individuals and their quest for autonomy are best understood through the humanities, because poets, novelists, playwrights, painters and sculptors all deal with individuals. Doctors, patients and the community should benefit from these insights". In practical terms, there should be increased selection of medical students from those with a training in the humanities; and the humanities "should be a part of medical education".

The implications of this thesis for medical practice and medical ethics are clearly described and explained. It will not be popular with those who put their trust in charters, in tighter financial controls, or even in guidelines, algorithms and "evidence-based medicine" (which can comprise only a small part of the totality of illness for which health care can be effective). But it is a view which has been largely expressed by those with no personal experience of the actualities of medical practice; now that it has been stated, and clearly stated, by a practising surgeon, it may gain more of the attention which it deserves. There must of course be preservation of what is scientifically established (and in spite of Popper, there are things in whose existence we can feel some confidence, such as genes and hormones); and the most skilled communication is flawed, when used to promulgate "what ain't so".

Are there faults? The book without faults remains to be written. A minor fault may be a certain tendency to

introduce unexplained marginalia, which do not affect the argument, and which (while expanding the list of references) may tend to confuse the reader. To give a concrete example of this, Husserl's phenomenology and Ricoeur's critique of it are cited on page 17, without explanation of their relevance. More seriously, but understandably in the light of the main thesis, the differences between the scientific and empathic aspects of medical practice are stressed, rather than their essential complementarity.

"Who is this book for?" – or, if you prefer it, "For whom is this book?" At the risk of presumption, not for the non-medical professional ethicist; and still less for an academic philosopher, especially anyone whose mind may still be nourished by the dead sea fruit of logical positivism. The material on the cover of the book, while not an affidavit, for once provides a good answer, claiming that the book "will be of interest to medical students and their teachers, clinicians, health policy planners, and other readers concerned about the direction of the medical profession". Understandably, the last of these categories would not admit of many exclusions; but the others, with the possible exception of health policy planners who might be upset by the real life flavour of the book, are "spot on". To them, I would commend it with some warmth.

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The International Assessment of Health-related Quality of Life: Theory, Translation, Measurement and Analysis

Edited by Sally Shumaker and Richard Berzon, Oxford, Rapid Communications of Oxford Ltd, 1995, 275 pages, £80.

Until recently it was only possible to judge the effectiveness of modern medicine by the criteria of death rates or clinical and laboratory indicators of disease. In the last twenty years or so an explosion of research activity has

occurred in relation to what is termed "health-related quality of life" (HRQOL). An enormous number of questionnaires and interview schedules have been produced by medical, epidemiological and social scientific investigators, designed to assess the personal significance of ill-health and the subjective benefits of health care interventions. This industry, an appropriate term in view of the scale of activity, eventually attracted the attention of philosophers and medical ethicists for two reasons. Firstly, questionnaires that were developed purported to measure the personal meaning of human states of well-being and illness. This has been the intellectual territory of philosophers since at least the time of Aristotle. Secondly measures of health-related quality of life achieved notoriety for one specific use to which they were put – to provide estimates for health economists of the relative utility of medical treatments in the context of utilitarian approaches to resource allocation in health care. A core interest for medical ethicists is the examination of moral principles underlying the allocation of scarce resources.

Sally Shumaker and Richard Berzon have edited a collection of essays on a subject that may well have provided a third reason for ethicists and philosophers to examine this burgeoning field of enquiry. The presupposition of almost all of the essays in this collection is that questionnaires can provide equivalent assessments of health-related quality of life across cultures. The answers to questions about well-being and function provided by middle class Bostonians can be treated as equivalent to those provided by the slum-dwellers of Calcutta. This will provoke many to think of longstanding philosophical questions about whether notions of well-being or of the value of life are universal or culture-specific. The main reason for this most recent development within the industry of HRQOL has been quite commercial in origin – the growing need for clinical trials of drugs to be conducted in larger numbers of countries with diverse languages.

The chapters describe in careful detail the meticulous processes whereby questionnaires such as the Nottingham Health Profile, the Sickness Impact Profile, the MOS SF-36 and EuroQol are translated from the original English to new languages and then field-tested for reliability and validity. The tone of almost all of the papers is strikingly pragmatic and

optimistic. Questionnaires can be and are produced that, for practical purposes, produce equivalent responses. Further research will resolve lingering reservations. To some extent the positive and practical tone of the work described is determined not just by its commercial origins but also by the fact that most work has been conducted in relatively compliant and homogeneous sections of European and North American societies. There are a few intellectual doubts reported in the volume. Naughton and Wiklund report evidence that the widely used Centers for Epidemiologic Studies - Depression (CES-D) scale does not produce patterns of depressive symptoms in some Asian American groups consistent with other cultural groups. Guyatt briefly suggests that the field reflects the "cultural hegemony" of middle-class American concerns before going on to suggest pragmatic research solutions. On the whole, similarities between cultures are far more apparent in this book than differences. It offers a powerful challenge to moral relativists, although the message is implicit, this not being the intention of the contributors.

While such work is confined to examining non-specific effects of drugs in the context of international randomised controlled trials, the cross-cultural thrust of much HRQOL may remain relatively uncontroversial. The current volume clearly, and in a most scholarly way, demonstrates the scientific caution and care of this new approach. If like the QALY, international assessments of HRQOL become involved in issues of choice about human life and resource allocation, we can expect a wider and more heated debate.

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Good Clinical Practice and Ethics in European Drug Research

Edited by Peter Bennett, Bath, Bath University Press, 1994, 159 pages, £30.

This edited collection arose out of a symposium, held in 1993, that looked at the impact of European

Community guidelines on good clinical practice (EC GCP) in European drug research. The EC GCP sets out a uniform standard for the ethical conduct of clinical trials. The collection examines the effect of applying this uniform standard and details the complexities that exist in the review process due to the large number of ethics committees that have been formed in the member states.

The proliferation of ethics committees is a pressing problem for multi-centred trials and some fascinating case studies are presented that graphically highlight both the time-consuming complexity of multi-centred applications and the often inadequate scientific and ethical evaluation of the intended trial. One team stated that even after their application was considered by 68 ethics committees in 12 European countries "certain basic questions and points concerning the ethics of the trial were not covered by any of the ethics committees" (page 64). The ethics committees also omitted to consider many of the points that are explicitly referred to in the EC GCP guidelines. Notably, information that an investigator was in a position to undertake the study was neither sent nor requested by *any* of the ethics committees and many of the committees not familiar with the drugs involved in the trial did not request further information, even though the existence of this information was referred to in the protocol. The team concluded: "It is difficult to understand on what basis these ethics committees were able to judge the relative benefits of ... [the] therapy" (page 58). This raises the issue of the effectiveness of any European GCP guidelines if there is no structure in place to ensure that committees rigorously apply these guidelines.

Some of the problems created by multi-centred trials could be addressed by a cross-Europe ethics committee that works in tandem with the local ethics committees. To provide this function the European Ethical Review Committee was set up in the late 1970s and draws its membership from different countries in Europe to give a supranational ethics review. The work and role of this committee is considered in the book.

The contributions are largely from medics and one concern of the book is to give an account of the ethical review process in a number of countries (Denmark, the Nordic countries, Eastern Europe and the USA). This

general overview provides a valuable insight into international differences. The collection also includes essays addressing: general issues in the ethical consideration of informed consent in clinical drug trials, ethical issues of adverse effects, and the problems created by special groups such as psychiatric and cancer patients. Furthermore, there is a discussion of how important it is that the membership of ethics committees fully understand the scientific issues raised by research protocols. This discussion concludes with a useful consideration of what kind of education should be provided for the membership to enhance their understanding of both the scientific and ethical aspects of research protocols.

As an appendix to the book the GCP for clinical trials on medicinal products in the European community is included in full (a useful reference for practitioners). The guidelines begin by stating that "the Declaration of Helsinki is the accepted basis for clinical trial ethics" (page 141). This gives an indication of the overall spirit of the guidelines but, as pointed out by one of the contributors, Oliver Guilloid, this can give rise to a certain amount of ambiguity. There are points where the two guidelines conflict, for instance the Helsinki Declaration allows for conduct of clinical research without informed consent (principle 1.II) whereas the EC GCP does not. It is submitted that only one set of guidelines should be kept and this should be the EC GCP as, in Guilloid's opinion, it is far better than the Helsinki Declaration.

This collection is a useful guide to how the ethical review process works in practice and provides an illuminating insight into regional differences. The consideration of the ethical dimensions of clinical research in a working context is an invaluable exercise, as often the abstract reiteration of ethical principles does not reflect the complexity of practical decision-making.

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Chronic Illness: From Experience to Policy

Edited by S K Toombs, D Barnard and R A Carson, Bloomington and Indianapolis, Indiana University Press, 1995, 221 pages, £23.50.